TRANSMITTAL LETTER TO THE UNITED STATES **DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A SUBMISSION UNDER 35 U.S.C. 371** 

ATTORNEY'S DOCKET NUMBER **SHIM-019** U.S. APPHICACION NO (15 rio) n, see 37 CFR 1.5) PRIORITY DATE CLAIMED

| INTERNATIONAL AP | PLICATION NO. |
|------------------|---------------|
| ID2004/049442    |               |

TITLE OF INVENTION

INTERNATIONAL FILING DATE 12/9/2004

December 12, 2003

| MEGSIN/RAGE/INOS-OVEREXPRESSING RENAL DISEASE MODEL ANIMALS AND METHODS FOR EVALUATING COMPOUNDS USING THE MODEL ANIMALS |   |  |  |  |  |  |  |  |  |
|--|---|--|--|--|--|--|--|--|--|
|  | NT(S) FOR DO/EO/US<br>A, TOSHIO KUROKAWA, KIYOSHI YAMAMOTO, HIROSHI OKAMOTO, HIROSHI  |  |  |  |  |  |  |  |  |
|  | herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:   |  |  |  |  |  |  |  |  |
| 1. 🛛   | This is a FIRST submission of items concerning a filing under 35 U.S.C. 371.  |  |  |  |  |  |  |  |  |
| 2. 🗌   | This is a SECOND or SUBSEQUENT submission of items concerning a submission under 35 U.S.C. 371.   |  |  |  |  |  |  |  |  |
| 3. 🔲   | This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below. |  |  |  |  |  |  |  |  |
| 4. 🛛   | The US has been elected (Article 31).   |  |  |  |  |  |  |  |  |
| 5. 🛛   | A copy of the International Application as filed (35 U.S.C. 371(c)(2)))   |  |  |  |  |  |  |  |  |
|  | a. 🔀 is attached hereto (required only if not communicated by the International Bureau).  |  |  |  |  |  |  |  |  |
|  | b.  has been communicated by the International Bureau.  |  |  |  |  |  |  |  |  |
|  | c.  is not required, as the application was filed in the United States Receiving Office(RO/US)  |  |  |  |  |  |  |  |  |
| 6.   | An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).  |  |  |  |  |  |  |  |  |
|  | a. 🔀 is attached hereto.  |  |  |  |  |  |  |  |  |
|  | b. has been previously submitted under 35 U.S.C. 154(d)(4).   |  |  |  |  |  |  |  |  |
| 7. 🛛   | Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))  |  |  |  |  |  |  |  |  |
|  | a. are attached hereto (required only if not communicated by the International Bureau).   |  |  |  |  |  |  |  |  |
|  | b.  have been communicated by the International Bureau.   |  |  |  |  |  |  |  |  |
|  | c. have not been made; however, the time limit for making such amendments has NOT expired.  |  |  |  |  |  |  |  |  |
|  | d. A have not been made and will not be made.   |  |  |  |  |  |  |  |  |
| 8. 🗌   | An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).   |  |  |  |  |  |  |  |  |
| 9. 🔲   | An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).  |  |  |  |  |  |  |  |  |
| 10.  | An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).                    |  |  |  |  |  |  |  |  |
| Items 1  | 11 to 20 below concern document(s) or information included:   |  |  |  |  |  |  |  |  |
| 11. 🔲  | An Information Disclosure Statement under 37 CFR 1.97 and 1.98.   |  |  |  |  |  |  |  |  |
| 12. 🔲  | An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.   |  |  |  |  |  |  |  |  |
| 13. 🛛  | A preliminary amendment.  |  |  |  |  |  |  |  |  |
| 14. 🛛  | An Application Data Sheet under 37 CFR 1.76.  |  |  |  |  |  |  |  |  |
| 15. 🛛  | A substitute specification.   |  |  |  |  |  |  |  |  |
| 16. 🗌  | A power of attorney and/or change of address letter.  |  |  |  |  |  |  |  |  |
| 17. 🛛  | A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821 - 1.825.  |  |  |  |  |  |  |  |  |
| 18. 🗌  | A second copy of the published International Application under 35 U.S.C. 154(d)(4).   |  |  |  |  |  |  |  |  |
| 19. 🔲  | A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).   |  |  |  |  |  |  |  |  |
| 20 🔯   | Other items or information; neetcard  |  |  |  |  |  |  |  |  |

This collection of information is required by 37 CFR 1.414 and 1.491-1.492. The information is required to obtain or retain a benefit by the public, which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 15 minutes to complete, including gathering information, preparing, and submitting the completed form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

AP3 Rec'd PCT/PTO 12 JUN 2005 PTO-1390 (Rev. 02-2005)
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

| Und   | er the Paperwork Reduct                        | tion Act of 1995,                  | no persons are required to res                    | pond to a   | a collection of inform   | nation unless it displays a va | ilid OMB control number. |  |
|---|--|------------------------------------|---|-------------|--------------------------|--------------------------------|--------------------------|--|
| U.S. APPLICATION NO. (If known, see 37 CFR 1.5) INTERNATIONAL APPLICATION NO.   |  |                                    |   |             | ATTORNEY'S DOCKET NUMBER |                                |                          |  |
| Topp (1985) 192004/018413   |  |                                    |   |             | SHIM-019                 |                                |                          |  |
| The following fees are submitted:   |  |                                    |   |             | CALCULATIONS             | PTO USE ONLY                   |                          |  |
| 21. Basic national fee (37 CFR 1.492(a))\$300.00  |  |                                    |   | \$300.00    | \$ 300.00                | 110 002 012                    |                          |  |
| 22. Examination   | on fee (37 CFR 1.492)                          | (c))                               |   |             |                          |                                |                          |  |
| If the written opinion  | prepared by ISA/US                             | or the internati                   | onal preliminary examinat<br>CT Article 33(1)-(4) | ion rep     | ort prepared by          | \$ 200.00                      |                          |  |
| All other situations  | ates all claims satisty                        | provisions of P                    | CT Article 33(1)-(4)                              | ••••••      | \$0<br>\$200.00          |                                |                          |  |
| 23. Search fee  | (37 CRF 1.492(b))                              |                                    |   |             |                          | \$ 500.00                      |                          |  |
| If the written opinion<br>IPEA/US indicates   | n of the ISA/US or<br>ates all claims satisfy: | the internation<br>provisions of P | al preliminary examination                        | n repo      | rt prepared by           | <b>V</b> 000.00                |                          |  |
| Search fee (37 CFR 1  | 1.445(a)(2)) has been                          | paid on the inte                   | emational application to the                      | e USPT      | O as an                  |                                |                          |  |
| International Searching Authority   |  |                                    |   |             |                          |                                |                          |  |
| communicated<br>All other situations  | to the US by the IB                            | ••••••                             |   | ••••••      | \$400.00<br>\$500.00     |                                |                          |  |
|   |  | - 21, 22 and 2                     |   | *********** |                          | \$ 1000.00                     |                          |  |
| Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing or computer program listing filed in an electronic medium). The fee is \$250 for each additional 50 sheets or paper or fraction thereof.           |  |                                    |   |             |                          |                                |                          |  |
|   |  | Number of                          | each additional 50 or frac                        |             |                          |                                |                          |  |
| Total Sheets  | Extra sheets                                   | thereof (n                         | ound up to a whole number                         | er)         | RATE                     |                                |                          |  |
| - 100 =   | /50 =  | <u> </u>                           |   |             | X \$250.00               | \$                             | <u> </u>                 |  |
| priority date (37 CFR   |  | th or declaration                  | n later than 30 months fro                        | om the e    | earliest claimed         | \$                             |                          |  |
| CLAIMS  | NUMBER   | FILED                              | NUMBER EXTRA                                      |             | RATE                     | \$                             |                          |  |
| Total Claims  | Total Claims - 20 = x \$50.00                  |                                    | × \$50.00   | \$          |                          |                                |                          |  |
| Independent Claims  |  | - 3=                               |   | ×           | \$200.00                 | \$                             |                          |  |
| MULTIPLE DEPEND   | ENT CLAIMS(S) (if a                            | oplicable)                         |   | 4           | + \$360.00               | \$                             |                          |  |
|   |  | T                                  | OTAL OF ABOVE C                                   | ALCU        | LATIONS =                | \$ 1000.00                     |                          |  |
| Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above are reduced by ½.   |  |                                    |   |             |                          |                                |                          |  |
|   |  |                                    |   | Šl          | JBTOTAL =                | \$ 1000.00                     |                          |  |
| Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(i)).   |  |                                    |   |             |                          | \$                             |                          |  |
|   |  |                                    | TOTAL   | NATIO       | NAL FEE =                | \$ 1000.00                     |                          |  |
|   |  |                                    | TOTAL FE  | ES EN       | NCLOSED =                | \$ 1000.00                     |                          |  |
|   |  |                                    |   |             |                          | Amount to be refunded:         | \$                       |  |
|   |  |                                    |   |             |                          | Amount to be                   | <u> </u>                 |  |
|   |  |                                    |   |             |                          | charged:                       | \$1000.00                |  |
| a. A check in   | the amount of \$                               | _ to cover the                     | above fees is enclosed.                           |             |                          |                                |                          |  |
| b. Please charge my Deposit Account No. 50-0815 in the amount of \$ to cover the above fees.  |  |                                    |   |             |                          |                                |                          |  |
| A duplicate copy of this sheet is enclosed.  c. The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any  |  |                                    |   |             |                          |                                |                          |  |
| overpayment to Deposit Account No. <u>50-0815</u> . A duplicate copy of this sheet is enclosed.  d. Fees are to be charged to a credit card. WARNING: Information on this form may become public. Credit card   |  |                                    |   |             |                          |                                |                          |  |
| Information should not be included on this form. Provide credit card information and authorization on PTO-2038.  NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and |  |                                    |   |             |                          |                                |                          |  |
| granted to restore the International Application to pending status.   |  |                                    |   |             |                          |                                |                          |  |
| SEND ALL CORRESPONDENCE TO:   |  |                                    |   |             |                          |                                |                          |  |
| Bozicevic, Field & Francis, LLP   |  |                                    |   |             |                          |                                | <del> </del>             |  |
| 1900 University<br>200  | Avenue, Suite                                  | zicevic                            |   |             |                          |                                |                          |  |
| East Palo Alto  |  |                                    |   |             |                          |                                |                          |  |
| California 28,807   |  |                                    |   |             |                          |                                |                          |  |
| 94303   |  |                                    |   |             |                          | RATION NUMBER                  |                          |  |

## EXPRESS MAIL LABEL NO. EV 686 490 234 US

## 24353 Customer Number **CERTIFICATION** To Be Assigned Application Number **REGARDING SEQUENCE** To Be Assigned Confirmation Number LISTING December 9, 2004 Intl. Filing Date First Named Inventor MIYATA, TOSHIO Address to: **Examiner Name** To Be Assigned **BOX PATENT APPLICATION** Commissioner for Patents Group Art Unit To Be Assigned P.O. Box 1450 SHIM-019 Attorney Docket Alexandria, VA 22313-1450

I hereby certify that the enclosed Sequence Listing is being submitted under 37 CFR §§ 1.821(c) and (e) in paper and computer readable form (Compact Disk labeled 'CRF').

As required by 37 CFR 1.821(f), I hereby state that the content of the paper and computer readable copy of the Sequence Listing, submitted in accordance with 37 C.F.R. §1.821(c) and (e) are the same.

I hereby certify that the enclosed submission includes no new matter. The Sequence Listing was prepared with the software FASTSEQ, and conforms to the Patent Office guidelines. Applicant respectfully submits that the subject application is in adherence to 37 CFR §§ 1.821-1.825.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number SHIM-019.

Respectfully submitted,

**BOZICEVIC, FIELD & FRANCIS LLP** 

Date:

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